4 QUALITY SYSTEM MANUALS AND CONTROL

4.1 Quality System Manuals

4.1.1 The only two official copies of any Quality System (QS) manual will be the signed hard copy held by the Manual Custodian and the electronic copy that is published on the Department's intranet.

4.1.2 QS manuals include but are not limited to

- This manual
- The Department Safety Manual
- Section Standard Operating Procedures (SOPs)/Technical Procedures Manuals
- Section Training Manuals
- Administrative Operating Procedures (AOPs)
- Regional Operating Procedures (ROPs)

4.1.3 Each page of a QS manual will have the same format as this manual. All QS manuals will follow the format of this manual:

- Page i: Title page of the manual
- Page ii: Signature page
- Page iii: Amendment page
- Page iv, etc.: Table of Contents
- Body of the manual

4.1.4 Each QS manual will have a unique title and will be signed on its cover page by the Issuer. All pages in QS manuals will follow the page format of this manual. The end of a section will be designated by "► **End**" justified on the right margin.

4.2 The Manual Custodian and the Issuer

4.2.1 The QAC is the **Manual Custodian** for all manuals issued under the Quality System. It is the responsibility of the Manual Custodian to ensure the following:

- The format of the manual is correct.
- New issues or amendments are promptly placed on the Intranet and appropriate staff notified.
- The master file of official manuals and the archive file are maintained (¶ 4.3).

4.2.2 The **Issuer** of a manual is the person who has responsibility for the content of the manual. Issuers are:

- This manual – Deputy Director.
- Safety Manual - QAC.
- Section Manuals - Section Chief.
- AOPs - Deputy Director.
- ROPs - Regional Laboratory Director.

4.2.3 It is the responsibility of the Issuer of the manual to ensure the following:

- The manual is prepared, correct, and coordinated (¶ 4.4.3).
- Amendments to the manual are prepared and coordinated in a timely manner.
- A hard copy and a disk of the manual or amendments are forwarded to the Manual Custodian.
- Appropriate staff is promptly notified of new issues or amendments.

- A documented review of the manual is completed at least annually.

4.3 Master File of QS Manuals

4.3.1 The Manual Custodian will maintain the hard copies of QS manuals.

4.3.2 The Manual Custodian will maintain electronic versions of QS manuals on the Department's Intranet for staff access.

4.3.3 The Manual Custodian will maintain an archive file where all superseded official copies are maintained (both the hard copy and the electronic copy if available).

4.3.4 Employees may download and print copies of manuals for personal use; however, these copies are unofficial.

4.4 Control of Changes to QS Manuals

4.4.1 The Issuer of the manual must approve the amendment to or a new version of a manual before it is disseminated to staff.

4.4.2 Manuals may be up-dated and re-issued as necessary but each manual is to be reviewed by the Issuer at least yearly (¶ 4.2.2). This review will be documented in a written memorandum to the Deputy Director. The QAC will maintain the file of memoranda of review.

4.4.3 All amendments to or new versions of a manual that are forwarded to the Manual Custodian for publication will have a reviewer's page containing the signature or e-mail concurrence of those by whom it was reviewed. As a minimum, the following are required:

4.4.3.1 For this manual, the Safety Manual, and Section Manuals, a review page containing the signature of the Director of Technical Services.

4.4.3.2 For AOPs, a review page containing the signature of the Department Director.

4.4.3.3 For ROPs, a review page that includes the signature of the Deputy Director.

4.5 New Issues of and Amendments to Manuals

4.5.1 The first issue of a manual will carry the numerical designation of Issue 1. Subsequent re-publications of the whole manual will be designated as Issue 2, Issue 3, etc. The superseded version will be archived (¶ 4.3.3).

4.5.2 Amendments to sections within a manual will be made by substituting the newly-amended section for the superseded section. Each amendment will be noted on the "Amendment Page" (page ii) of the manual. The section change will be identified by an alphabetic designator following the section number. For example, the first amendment of section 1 would carry the number "1A"; the second amendment of section 5, "5B".

4.5.3 Amendments to appendices, etc. will be similarly made and noted on the "Amendment Page". They will be identified by an added alternating alphanumeric designator following the procedure used for generating sub-item numbers for evidence (¶ 13.3.3.3). For example, the third amendment of appendix A would carry the number "A3".

4.5.4 If a change must be made quickly, the Deputy Director may authorize an e-mail change to the manual; however, this change must be formally documented (¶ 4.4) and published on the Department's Intranet within one week of the date of the e-mail.

4.6 Standard Operating Procedures, Administrative Operating Procedures, and Regional Operating Procedures

4.6.1 Standard Operating Procedures (SOPs) and Administrative Operating Procedures (AOPs) are documents that provide detailed directions for the performance of employees' duties. SOPs are written by Section Chiefs to describe technical and quality assurance procedures within their Sections, and constitute the bulk of their Technical Procedures Manuals. AOPs are written by management to describe administrative procedures, including Department–wide quality assurance "procedures" largely written as requirements to be addressed in each Section's Technical Procedures Manual. AOPs are appendices to this manual.

4.6.2 Regional Operating Procedures (ROPs) are documents promulgated in a regional laboratory to provide guidance on matters unique to that laboratory; e.g., appointment of employees to various additional duties, security issues, evacuation plan, etc. ROPs are written by the appropriate Laboratory Director.

4.6.3 SOPs, AOPs and ROPs are controlled documents. The control of SOPs, as sections of Technical Procedures Manuals, is addressed in ¶ 17.3.2 of this manual. AOPs, as appendices to this manual, are treated as sections of this manual for purposes of generation and revision. ROPs are controlled by the appropriate Laboratory Director.

► **End**